

M-H

PENT COOPERATION TREA

PCT

NOTIFICATION OF ELECTION
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
 United States Patent and Trademark
 Office
 Box PCT
 Washington, D.C.20231
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in its capacity as elected Office

Date of mailing (day/month/year) 06 March 2000 (06.03.00)	
International application No. PCT/US99/12909	Applicant's or agent's file reference 15280-356-1PC
International filing date (day/month/year) 08 June 1999 (08.06.99)	Priority date (day/month/year) 11 June 1998 (11.06.98)
Applicant PASTAN, Ira, H. et al	

1. The designated Office is hereby notified of its election made:

 in the demand filed with the International Preliminary Examining Authority on:

08 January 2000 (08.01.00)

 in a notice effecting later election filed with the International Bureau on:2. The election was was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Nestor Santesso Telephone No.: (41-22) 338.83.38
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 47/48		A3	(11) International Publication Number: WO 99/64073
			(43) International Publication Date: 16 December 1999 (16.12.99)
(21) International Application Number: PCT/US99/12909		(74) Agents: STORELLA, John, R. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).	
(22) International Filing Date: 8 June 1999 (08.06.99)		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(30) Priority Data: 60/088,860 11 June 1998 (11.06.98) US		(71) Applicant (for all designated States except US): THE GOVERNMENT OF THE UNITED STATES, represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; Bethesda, MD 20892 (US).	
(72) Inventors; and (75) Inventors/Applicants (for US only): PASTAN, Ira, H. [US/US]; 11710 Beall Mountain Road, Potomac, MD 20854 (US). BERA, Tapan, K. [US/US]; 18302 Uvy Oak Terrace, Gaithersberg, MD 20877 (US). KENNEDY, Paul, E. [US/US]; 735 Easly Street, Silver Spring, MD 20910 (US). BERGER, Edward, A. [US/US]; 5820 Inman Park Circle #230, Rockville, MD 20852 (US). BARBAS, Carlos, F., III [US/US]; 7081 Weller Street, San Diego, CA 92122 (US).		<p>Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>	
		(88) Date of publication of the international search report: 10 February 2000 (10.02.00)	

(54) Title: RECOMBINANT IMMUNOTOXIN DIRECTED AGAINST THE HIV-1 GP120 ENVELOPE GLYCOPROTEIN

(57) Abstract

This invention provides an immunotoxin that specifically binds to and kills cells displaying an HIV gp120 coat protein. The immunotoxin comprises an anti-gp120 antibody directed to the conserved CD4 binding site of gp120 attached to a cytotoxin e.g. a *Pseudomonas* exotoxin. In one preferred embodiment the immunotoxin is a recombinantly expressed fusion protein comprising a single chain Fv region attached to a modified *Pseudomonas* exotoxin (3B3(Fv)-PE38).

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DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12909

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K47/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US</p> <p>BERA, TAPAN K. ET AL: "Specific killing of HIV-infected lymphocytes by a recombinant immunotoxin directed against the HIV-1 envelope glycoprotein" retrieved from STN Database accession no. 129:229342 XP002125548 abstract & MOL. MED. (N. Y.) (1998), 4(6), 384-391</p> <p>-----</p> <p>US 5 834 599 A (SUN BILL NAI-CHAU ET AL) 10 November 1998 (1998-11-10) claims; examples</p> <p>-----</p> <p>-/-</p>	1-56
P, X		1

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

14 December 1999

29/12/1999

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Berte, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12909

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication where appropriate, of the relevant passages	Relevant to claim No.
A	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US</p> <p>BERA, TAPAN K. ET AL: "A bivalent disulfide-stabilized Fv with improved antigen binding to erbB2" retrieved from STN Database accession no. 129:270188 XP002125549 abstract & J. MOL. BIOL. (1998), 281(3), 475-483 , ---</p>	1,6,12, 13,15, 25,28
A	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US</p> <p>PINCUS, SETH H. ET AL: "In vitro effects of anti-HIV immunotoxins directed against multiple epitopes on HIV type 1 envelope glycoprotein 160" retrieved from STN Database accession no. 125:185279 XP002125550 abstract & AIDS RES. HUM. RETROVIRUSES (1996), 12(11), 1041-1051 , ---</p>	1-56
Y	<p>LEE H. PAI ET AL.: "Anti-tumor activities of immunotoxins made of monoclonal antibody B3 and various forms of Pseudomonas exotoxin" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 88, April 1998 (1998-04), pages 3358-3362, XP002125579 WASHINGTON US cited in the application figure 3; table 1 ---</p>	1-56
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X	US 5 458 878 A (CHAUDHARY VIJAY K ET AL) 17 October 1995 (1995-10-17)	1
Y	cited in the application claims 1,2,7,9 ---	1-56

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/12909

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97 13529 A (US HEALTH ;KUAN CHIEN TSUN (US); PASTAN IRA (US)) 17 April 1997 (1997-04-17) claims 1,2,9,37 -----	1-56

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 12909

B x I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 33-51 because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 33-51 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US 99/12909

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5834599	A 10-11-1998	AT 122237 T		15-05-1995
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		EP 0861091 A		02-09-1998

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 47/48		A3	(11) International Publication Number: WO 99/64073 (43) International Publication Date: 16 December 1999 (16.12.99)
<p>(21) International Application Number: PCT/US99/12909</p> <p>(22) International Filing Date: 8 June 1999 (08.06.99)</p> <p>(30) Priority Data: 60/088,860 11 June 1998 (11.06.98) US</p> <p>(71) Applicant (for all designated States except US): THE GOVERNMENT OF THE UNITED STATES, represented by THE SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES [US/US]; Bethesda, MD 20892 (US).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): PASTAN, Ira, H. [US/US]; 11710 Beall Mountain Road, Potomac, MD 20854 (US). BERA, Tapan, K. [US/US]; 18302 Uvy Oak Terrace, Gaithersberg, MD 20877 (US). KENNEDY, Paul, E. [US/US]; 735 Easly Street, Silver Spring, MD 20910 (US). BERGER, Edward, A. [US/US]; 5820 Inman Park Circle #230, Rockville, MD 20852 (US). BARBAS, Carlos, F., III [US/US]; 7081 Weller Street, San Diego, CA 92122 (US).</p>		<p>(74) Agents: STORELLA, John, R. et al.; Townsend and Townsend and Crew LLP, 8th floor, Two Embarcadero Center, San Francisco, CA 94111-3834 (US).</p> <p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 10 February 2000 (10.02.00)</p>	
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P, X	<p>US 5 834 599 A (SUN BILL NAI-CHAU ET AL) 10 November 1998 (1998-11-10) claims; examples</p> <p>---</p> <p>-/-</p>	1

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Date of the actual completion of the international search

14 December 1999

Date of mailing of the international search report

29/12/1999

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Berte, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12909

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INTERNATIONAL SEARCH REPORT

International application No.

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4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is
restricted to the invention first mentioned in the claims: it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/12909

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 5834599	A 10-11-1998	AT 122237	T	15-05-1995	
		CA 1339857	A	05-05-1998	
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		EP 0366718	A	09-05-1990	
		JP 2520464	B	31-07-1996	
		JP 3504556	T	09-10-1991	
		WO 8809181	A	01-12-1988	
		US 5981278	A	09-11-1999	
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		EP 0861091	A	02-09-1998	

PENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 15280-356-1PC	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 99/ 12909	International filing date (day/month/year) 08/06/1999	(Earliest) Priority Date (day/month/year) 11/06/1998
Applicant THE GOVERNMENT OF THE UNITED STATES as represented		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. **Certain claims were found unsearchable** (See Box I).

3. **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

RECOMBINANT IMMUNOTOXIN DIRECTED AGAINST THE HIV-1 GP120 ENVELOPE GLYCOPROTEIN

5. With regard to the **abstract**,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 12909

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 33-51
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 33-51
are directed to a method of treatment of the human/animal
body, the search has been carried out and based on the alleged
effects of the compound/composition.
2. Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such
an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all
searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment
of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report
covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12909

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K47/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category ^o	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US</p> <p>BERA, TAPAN K. ET AL: "Specific killing of HIV-infected lymphocytes by a recombinant immunotoxin directed against the HIV-1 envelope glycoprotein" retrieved from STN Database accession no. 129:229342 XP002125548 abstract & MOL. MED. (N. Y.) (1998), 4(6), 384-391</p> <p>,</p> <p>---</p> <p>US 5 834 599 A (SUN BILL NAI-CHAU ET AL) 10 November 1998 (1998-11-10) claims; examples</p> <p>----</p> <p>-/-</p>	1-56
P, X		1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

^o Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

14 December 1999

29/12/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Berte, M

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12909

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US BERA, TAPAN K. ET AL: "A bivalent disulfide-stabilized Fv with improved antigen binding to erbB2" retrieved from STN Database accession no. 129:270188 XP002125549 abstract & J. MOL. BIOL. (1998), 281(3), 475-483 , ----	1,6,12, 13,15, 25,28
A	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US PINCUS, SETH H. ET AL: "In vitro effects of anti-HIV immunotoxins directed against multiple epitopes on HIV type 1 envelope glycoprotein 160" retrieved from STN Database accession no. 125:185279 XP002125550 abstract & AIDS RES. HUM. RETROVIRUSES (1996), 12(11), 1041-1051 , ----	1-56
Y	LEE H. PAI ET AL.: "Anti-tumor activities of immunotoxins made of monoclonal antibody B3 and various forms of Pseudomonas exotoxin" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 88, April 1998 (1998-04), pages 3358-3362, XP002125579 WASHINGTON US cited in the application figure 3; table 1 ----	1-56
X	DATABASE CHEMABS 'Online! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US MATSUSHITA, SHUZO ET AL: "Selective killing of HIV-infected cells by anti-gp120 immunotoxins" retrieved from STN Database accession no. 112:151331 XP002125551 abstract & AIDS RES. HUM. RETROVIRUSES (1990), 6(2), 193-203 , ----	1
X	US 5 458 878 A (CHAUDHARY VIJAY K ET AL) 17 October 1995 (1995-10-17) cited in the application	1
Y	claims 1,2,7,9 ----	1-56
		-/-

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/12909

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97 13529 A (US HEALTH ;KUAN CHIEN TSUN (US); PASTAN IRA (US)) 17 April 1997 (1997-04-17) claims 1,2,9,37 -----	1-56



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Dossier: 09673707

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Total number of pages: 1

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